



Food and Drug Administration
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GE Healthcare
% Mr. Mounir Zaouali
Regulatory Affairs Leader
Oskar-Schlemmer-Str. 11
Munich D-80807
GERMANY

March 26, 2015

Re: K143361
Trade/Device Name: MammoWorkstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 4, 2015
Received: March 9, 2015

Dear Mr. Zaouali:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. A faint, large "FDA" watermark is visible in the background behind the signature.

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K143361

Device Name
MammoWorkstation

Indications for Use (Describe)

MammoWorkstation is designed to assist radiologists in conducting primary diagnostic review for diagnostic and screening mammography through flexible and interactive manipulation of multi-modality softcopy images.

It provides image review, manipulation, analysis, post-processing and printing capabilities that support image management display needs in the medical environment.

MammoWorkstation is designed to give easy and economic access to and display of multi-modality softcopy images, structured reports, and CAD results through interfaces to various image storage devices using DICOM or similar interface standards. It supports creation of structured reports according to the DICOM breast imaging report templates.

MammoWorkstation supports teleradiology and teleconferencing providing access to multi-modality softcopy images and structured reports in multiple locations within and outside the hospital.

Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless approved for use in digital mammography.

Display monitors used for primary diagnostic interpretation of mammographic images must be approved for use in digital mammography.

All images sent to or imported in the Mammoworkstation must conform to regulatory requirements. Image quality must conform with applicable quality guidelines. All modalities must be certified for soft-copy reading.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

<u>Date:</u>	March 24, 2015
<u>Submitter:</u>	GE Healthcare (Image Diagnost International) Oskar-Schlemmer-Str. 11; 80807 München, Germany
<u>Primary Contact Person:</u>	Mounir Zaouali, RAC Regulatory Affairs Leader GE Healthcare, 283 RUE DE LA MINIERE 78530 BUC – FRANCE Phone : + 33 1 30 70 45 39 Fax : + 33 1 30 70 41 40 Mounir.Zaouali@ge.com
<u>Secondary Contact Person:</u>	Gregory Pessato Regulatory Affairs Leader GE Healthcare, 283 RUE DE LA MINIERE 78530 BUC – FRANCE Phone : + 33 1 30 70 93 16 Fax : + 33 1 30 70 41 40 Gregory.Pessato@ge.com
<u>Device Trade Name:</u>	MammoWorkstation
<u>Common/Usual Name:</u>	Medical imaging software
<u>Classification Names:</u>	Picture archiving and communication system Class II CFR 892.2050 System, Image Processing, Radiological,
<u>Product Code:</u>	LLZ
<u>Predicate Device(s):</u>	MammoWorkstation (K123575)
<u>Device Description:</u>	<p>The MammoWorkstation is a medical image review workstation software for diagnostic and screening mammography.</p> <p>MammoWorkstation has the capability to review Digital Breast Tomosynthesis (DBT) images that are compatible with DICOM</p>



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510(k) Premarket Notification Submission

	<p>Breast Tomosynthesis Image Storage.</p> <p>A synthesized 2D image, called V-Preview, is generated from the GE DBT set by MammoWorkstation and can be displayed before or during the diagnostic interpretation review of the DBT set. It can be used for the pre-review of the DBT set or as additional image but does not replace the FFDM image.</p> <p>It is a software product</p>
<u>Intended Use:</u>	<p>MammoWorkstation is designed to assist radiologists in conducting primary diagnostic review for diagnostic and screening mammography through flexible and interactive manipulation of multi-modality softcopy images.</p> <p>It provides image review, manipulation, analysis, post-processing and printing capabilities that support image management display needs in the medical environment.</p> <p>MammoWorkstation is designed to give easy and economic access to and display of multi-modality softcopy images, structured reports, and CAD results through interfaces to various image storage devices using DICOM or similar interface standards. It supports creation of structured reports according to the DICOM breast imaging report templates.</p> <p>MammoWorkstation supports teleradiology and teleconferencing providing access to multi-modality softcopy images and structured reports in multiple locations within and outside the hospital.</p> <p>Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless approved for use in digital mammography.</p> <p>Display monitors used for primary diagnostic interpretation of mammographic images must be approved for use in digital mammography.</p> <p>All images sent to or imported in the MammoWorkstation must conform to regulatory requirements. Image quality must conform with applicable quality guidelines. All modalities must be certified for soft-copy reading.</p>



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<p><u>Technology:</u></p>	<p>MammoWorkstation is software product. It is designed to run on a standard workstation with a minimum of three monitors, one control monitor and high-resolution monitor (s) that are cleared for mammography review.</p> <p>It runs on Windows Operating System.</p> <p><u>Comparison of technological characteristics with the predicate device</u></p> <p>Adequate display and manipulation for the review of Mammography and DBT images are the technological principles for both the subject and predicate device.</p> <p>The main differences between the subject and the predicate device are :</p> <p>V-Preview images on the predicate device were used for pre-review of the breast before diagnostic review of the DBT set of images.</p> <p>To enhance the radiology workflow, the subject device has incorporated the following changes:</p> <ul style="list-style-type: none"> • The V-Preview images will be labeled as “2D: Synthesized” and “V-Preview For navigation use only does not replace FFDM” to distinguish them from non-synthesized images. • V-Preview images can be annotated and printed or transferred to a PACS for storage or viewing in alternate locations. • In addition to the standard MammoWorkstation configuration, V-Preview images can be generated by the DicomShuttle configuration.
<p><u>Determination of Substantial Equivalence:</u></p>	<p><u>Summary of Non-Clinical Tests:</u></p> <p>The MammoWorkstation and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:</p>



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510(k) Premarket Notification Submission

	<ul style="list-style-type: none">• Risk Analysis• Requirements Reviews• Design Reviews• Testing on unit level (Module verification)• Integration testing (System verification)• Performance testing (Verification)• Safety testing (Verification)• Simulated use testing (Validation)
<u>Conclusion:</u>	GE Healthcare considers the MammoWorkstation to be as safe, as effective, and performance is substantially equivalent to the predicate device.